Care Management for High Cost Beneficiaries (CMHCB) Demonstration

Frequently Asked Questions

Table of questions	Page
General information	4
Is the CMHCB demonstration authorized by the Medicare Modernization Act?	4
What is the date the award announcement will be made? (11/10/04)	4
When does the demonstration actually start operations? (11/10/04)	4
Is the recording or transcript of the October 29 conference call available? (11/10/04)) 4
Application process	4
Does CMHCB require a letter of intent to be filed prior to the application deadline?	4
Is the application due date 90 days from when I receive the sample data file?	4
Financial / payment arrangements	5
May applicants propose both an administrative/care management fee and a gain- sharing arrangement or must they choose one or the other?	5
Can you provide an example of how the savings guarantee might work? (12/1/04) Will extremely high cost outlier cases be included in the determination/calculation of savings? (12/1/04)	5 of 6
Will the same method of calculating savings be used for all years of the demonstration? (12/1/04)	6
Will the effect of CMHCB interventions on total expenditures (including Medicare, Medicaid, MediGap, and out-of-pocket payments) be evaluated? (12/1/04)	6
Sample data set	6
Are there zip code level data available for the sample data set?	6
Are there hospital level data available for the sample data set?	6
Does the population in the sample data set contain beneficiaries who died or disenrolled?	7
Is it possible to obtain additional data from the national Medicare 5 Percent sample file?	7

Eligible organizations and populations	7
Are acute care and integrated hospital systems allowed to participate?	7
Are Medicare beneficiaries residing in nursing homes or skilled nursing facilities	7
eligible to participate in the demonstration?	
What does CMS consider a "high-risk" Hierarchical Condition Category (HCC) risk score? (11/10/04)	7
Are children an eligible population?	7
Are there any specific diagnoses or co-morbidities the CMHCB demonstration is	7
trying to target or exclude?	
May applicants include dual-eligible beneficiaries in the population set for CMHCB? (11/10/04)	8
Will beneficiaries enrolled in the demonstration who die or otherwise become	8
ineligible disenroll be "replaced" through additional recruitment. (11/10/04)	
Will CMS allow continued management of CMHCB beneficiaries if they enter hospice? (11/10/04)	8
Are there geographic areas of the country where beneficiary populations are blocked	8
from participating in CMHCB because of other CMS programs or demonstration projects? (11/10/04)	
Can a beneficiary specify an age range to target or exclude? (For example, could a	9
proposal focus enrollment for beneficiaries over 90 years of age, or between 70	
and 85 years of age?) (12/1/04)	
For the practice-based model, what kind of historical/past relationship does the	9
beneficiary need to have with the provider or providers included in a consortium arrangement? (12/1/04)	
In the practice-based model, would control groups be made up of patients with no	9
current relationship to the provider organization? (12/1/04)	0
May provider-based applicants propose a longer enrollment period than the six months described in the solicitation? (12/1/04)	9
What should provider-based applicants include in a recruitment enrollment design? (12/1/04)	10
Will CMS allow a two-pronged approach (a combined provider and population based) method to enroll beneficiaries? (12/15/04)	10
Will CMS allow a provider-based intervention group with multiple sites, enrolling a	10
smaller number of beneficiaries in each site and sufficient size overall? (12/15/04)	
Will CMS allow a geographic overlap with the CMHCB Demonstration and other	10
demonstrations (e.g., BIPA Disease Management) or the Chronic Care	
Improvement Program (CCIP)? (12/15/04)	11
Will CMS allow applicants to select all beneficiaries without targeting select diagnoses? (12/15/04)	11
Will CMS consider awarding a physician-driven project in multiple high inpatient	11
cost cities? (12/15/04)	11
Will CMHCB Demonstration awardees be able to start enrolling beneficiaries by	11
March 1, 2005? (12/15/04)	
Will CMS consider continuous enrollment (replacement) of beneficiaries?	12
(12/15/04)	

enefits, Services and Provider Contracts	12
Will CMS allow awardees to waive the beneficiary co-payments for covered	12
services? (11/10/04)	
Will CMS allow the awardee to provide coverage of prescription drugs prior to the implementation of Medicare Part D in 2006? (11/10/04)	12
Will CMS allow awardees to provide covered and/or non-covered services (e.g., transportation, personal assistance) to CMHCB beneficiaries? (11/10/04)	12
Will CMS allow awardees to waive the requirement for a three-day inpatient hospitalization prior to admission to a skilled nursing facility or other exclusion and conditions of coverage under the FFS program? (11/10/04)	13
Would CMS allow awardees to provide primary care physicians an incentive for comanagement of their patients who are in the intervention group? (11/10/04)	13
Are applicants required to have all provider contracts signed and in place prior to the application due date? (12/1/04)	13
Management and Contractual Issues	13
Will awardees be allowed to create the letters sent to potential demonstration beneficiaries? (11/10/04)	13
Will awardees be allowed to contact primary care physicians regarding patients identified in the intervention group? (11/10/04)	14
Please describe the two methods that applicants may propose for forming intervention and control groups. (11/10/04)	14
If a primary care physician wants to refer a patient qualifying for the demonstration but who was not listed in the original data set, would CMS allow the awardee to accept this patient with CMS then identifying a matched control? (11/10/04)	14
Englandian	15
Evaluation Is the evaluation of the demonstration tied to the financial shared savings? (12/1/04)	15
Is the evaluation of the demonstration tied to the financial shared savings? $(12/1/04)$ What is the purpose of Evaluation? $(12/1/04)$	15
Will the programs be evaluated compared to each other? (12/1/04)	15
What will be included in the evaluation, and will CMS conduct it? (12/1/04)	16
What data will be used to evaluate the program, and can applicants suggest criteria for control groups and satisfaction surveys? (12/1/04)	16
Will the evaluations be conducted each year, or only at the end of the demonstration? $(12/1/04)$	16

General information

Q. Is the CMHCB demonstration authorized by the Medicare Modernization Act?

A. The CMHCB demonstration is not associated with the Medicare Modernization Act (MMA). This demonstration is an initiative of the Centers for Medicare & Medicaid Services (CMS).

Q. What is the date the award announcement will be made? (11/10/04)

A. The announcement of awards will be made when the review of applications is complete. No fixed date has been set. Review of proposals is expected to require 30 to 60 days (or more) depending on the number of proposals that we receive.

Q. When does the demonstration actually start operations? (11/10/04)

A. The demonstration will begin after the review of applications, the successful completion of contract negotiations with the selected applicants, the procurement of any necessary waivers and approvals (e.g., from the Office of Management and Budget) and the identification of intervention and control groups. There is no fixed date by which the demonstration will commence.

Q. Is the recording or transcript of the October 29 conference call available? (11/10/04)

A. Neither a recording nor a transcript of the October 29 conference call is available. However, we are continuing to post questions and answers on the web site.

Application process

Q. Does CMHCB require a letter of intent to be filed prior to the application deadline?

A. No, a letter of intent is not required.

Q. Is the application due date 90 days from when I receive the sample data file?

A. No, the due date is 90 days after the notice announcing the demonstration was published in the Federal Register. The application must be received by CMS by 5:00 PM Eastern Time on January 4, 2005.

Financial / payment arrangements

- Q. May applicants propose both an administrative/care management fee and a gainsharing arrangement or must they choose one or the other?
 - A. Applicants may propose an administrative/care management fee, a gain-sharing arrangement, or a combination of both. All payment proposals must guarantee a net savings of 5 percent. Net savings will be calculated by comparing fee-for-service (FFS) payments for the control group to FFS payments plus any administrative or care management fees for the intervention group. The administrative or care management fees will be held at risk for the amount of any realized net savings less than 5 percent.

Q. Can you provide an example of how the savings guarantee might work? (12/1/04)

A. There are four examples of how the savings standard might work in the handout material used for the 10/29/04 Teleconference. The Exhibits are posted on the CMHCB website. http://www.cms.hhs.gov/researchers/demos/cmhcb_slides.pdf

All four examples assume that the control group incurs claims of \$1,000 per member per month. The five percent savings guarantee means that the savings standard is \$950. That is, total costs for the intervention group must not be greater than \$950.

In the first example, the CMHCB awardee exceeds the savings standard and no refund is due. Its claim costs are only \$800 PMPM (20% lower than the claims costs for the control group). The awardee was paid an administrative/CM fee of \$100 PMPM. Its total costs are, therefore, \$900 PMPM. This leaves \$50 PMPM to be divided between CMS and the CMHCB awardee if a shared savings is negotiated.

In the second example, the CMHCB awardee meets, but does not surpass, the savings standard. Its claim costs are only \$850 PMPM (15% lower than the claims costs for the control group). The awardee was paid an administrative/CM fee of \$100 PMPM. Its total costs are, therefore, \$950 PMPM or exactly equal to the savings standard. No refund is due.

In the third example, the CMHCB awardee only partially meets the savings standard. Its claim costs are only \$900 PMPM (10% lower than the claims costs for the control group). The awardee was paid an administrative/CM fee of \$100 PMPM. Its total costs are, therefore, \$1,000 PMPM, or \$50 PMPM above the savings standard. The CMHCB will need to refund \$50 PMPM to CMS as a recovery of unearned administrative/CM fees.

In the final example, the CMHCB awardee fails to even partially achieve the savings standard. Its claim costs are \$950 PMPM (5% lower than the claims costs for the control group). The awardee was paid an administrative/CM fee of \$100 PMPM. Its total costs are, therefore, \$1,050 PMPM or \$100 PMPM above the savings standard. The CMHCB will need to refund its entire \$100 PMPM administrative/CM fee to CMS.

Q. Will extremely high cost outlier cases be included in the determination/calculation of savings? (12/1/04)

A. We recognize the problem that may be caused by beneficiaries who incur extraordinarily high costs. For example a single enrollee who incurs claims of \$1,000,000 will increase the average PMPM cost for a population of 1,000 beneficiaries by more than \$80. We have not adopted a specific policy on handling extraordinarily high cost cases and are willing to consider a variety of methods. Applicants should describe in their proposal how this risk might be limited within their population. Provisions for handling extraordinarily costly cases in the evaluation of savings may be included in the cooperative agreements with the selected CMHCB organizations.

Q. Will the same method of calculating savings be used for all years of the demonstration? (12/1/04)

A. We expect the final calculation of savings to be based on the cumulative or aggregate expenditures, PMPM, for the entire three-year period covered by the demonstration. An applicant may propose to share savings only for a portion of this period. However, the savings standard applies to the entire three-year period. That is, if the savings target is not achieved for the entire three-year period covered by the demonstration, in aggregate, there will be no savings available for sharing. The specific provisions of a proposed method of sharing savings, if any, will be negotiated with each awardee.

Q. Will the effect of CMHCB interventions on total expenditures (including Medicare, Medicaid, MediGap, and out-of-pocket payments) be evaluated? (12/1/04)

A. CMS plans on evaluating the impact of CMHCB demonstrations on Medicare outlays. An awardee may work with states to examine the effect of their intervention on Medicaid expenditures. However, the application of the savings standards will be based on Medicare claims alone.

Sample data set

Q. Are there zip code level data available for the sample data set?

A. The CMHCB demonstration sample data file includes only the state in which the beneficiary lives. Zip code data are not available.

Q. Are there hospital level data available for the sample data set?

A. The CMHCB demonstration sample data file provides summary claims data information for each beneficiary. Hospital level data are not available.

Q. Does the population in the sample data set contain beneficiaries who died or disenrolled?

A. The sample file was developed as a cohort of fee-for-service beneficiaries continuously enrolled throughout calendar years 1999 and 2000. Beneficiaries who died in 1999 or 2000 are not included in the sample data set. The file does include and identify beneficiaries who died in 2001.

Q. Is it possible to obtain additional data from the national Medicare 5 Percent sample file?

A. The only data that are available through the CMHCB demonstration solicitation are contained in the sample data set.

Eligible organizations and populations

- Q. Are acute care and integrated hospital systems allowed to participate?
 - A. Yes, acute care and integrated hospital systems are eligible to participate.
- Q. Are Medicare beneficiaries residing in nursing homes or skilled nursing facilities eligible to participate in the demonstration?
 - A. Yes, nursing home and skilled nursing facility residents are eligible to participate.
- Q. What does CMS consider a "high-risk" Hierarchical Condition Category (HCC) risk score? (11/10/04)
 - A. For purposes of this demonstration, we have defined a high-risk HCC risk score as 1.7 or greater.
- Q. Are children an eligible population?
 - A. Yes, children who are high-cost and / or high-risk Medicare fee-for-service beneficiaries may be included in the CMHCB demonstration.
- Q. Are there any specific diagnoses or co-morbidities the CMHCB demonstration is trying to target or exclude?
 - A. No, the CMHCB demonstration does not target or exclude specific diagnoses. The intent of the demonstration is to identify and provide care management services for fee-for-service Medicare beneficiaries with high-cost and / or high-risk conditions. Within the high-cost and /or high-risk population, applicants may propose their own diagnoses, demographic and other demonstration parameters.

Q. May applicants include dual-eligible beneficiaries in the population set for CMHCB? (11/10/04)

A. Yes, beneficiaries receiving benefits from both Medicare and Medicaid are eligible to participate in the CMHCB demonstration. However, only those dual-eligible enrolled in the traditional fee-for-service Medicare program may be included.

Q. Will beneficiaries enrolled in the demonstration who die or otherwise become ineligible disenroll be "replaced" through additional recruitment. (11/10/04)

A. CMS understands that a significant percentage of the beneficiaries enrolled in the CMHCB demonstration will die or otherwise become ineligible and that this reduction in the number of participants has evaluation implications for the interventions and business implications for the awardees. Proposals should address the issue. The extent to which and methods by which the panel of beneficiaries enrolled in the demonstration can be replenished will be subject to negotiation between CMS and the awardees.

Q. Will CMS allow continued management of CMHCB beneficiaries if they enter hospice? (11/10/04)

A. While current enrollees in a hospice program are not eligible for the CMHCB demonstration, a CMHCB organization may continue to provide services to and receive payment for beneficiaries who later enroll in a hospice program. However, because palliative and end-of-life care are integral components of hospice care, the CMHCB awardee should coordinate its activities with the beneficiary's hospice. CMHCB awardees should also understand that beneficiaries who opt for hospice benefits may choose to discontinue their participation in the CMHCB demonstration.

Q. Are there geographic areas of the country where beneficiary populations are blocked from participating in CMHCB because of other CMS programs or demonstration projects? (11/10/04, 12/1/04)

A. No geographic area is completely excluded at the present time. However, there are limitations on the population that is available for enrollment in a CMHCB demonstration in some areas. For example, Los Angeles, San Francisco, Phoenix, and San Antonio have beneficiaries with congestive heart failure (CHF) and coronary artery disease (CAD) who are not eligible to participate in the CMHCB demonstration. In other areas, the award of Chronic Care Improvement Program (CCIP) contracts may limit the eligibility of beneficiaries with CHF, chronic obstructive pulmonary disease (COPD), or Diabetes to participate in the CMHCB.

Provider-based projects in which a medical group or provider consortium seeks to enroll its established patients in a CMHCB demonstration may not be subject to these same restrictions. Prospective applicants who have questions regarding a specific geographic area should call Randy Thomas, Project Officer, at 410-786-6578. (12/1/04)

- Q. Can a beneficiary specify an age range to target or exclude? (For example, could a proposal focus enrollment for beneficiaries over 90 years of age, or between 70 and 85 years of age?) (12/1/04)
 - A. An applicant may propose age-related exclusion or inclusion criteria if supported by evidence or experience showing that the proposed intervention is ineffective for patients in the excluded age groups and / or effective only for patients in the included age groups.
- Q. For the practice-based model, what kind of historical/past relationship does the beneficiary need to have with the provider or providers included in a consortium arrangement? (12/1/04)
 - A. The practice based model is intended for use by providers or groups of providers with an established relationship to a group of beneficiaries where using a population-based model is not possible. We have not developed specific criteria for determining that such a relationship exists. Generally, an "established relationship" should involve more than a single visit to a physician. However, an intervention targeting beneficiaries with significant medical events such as an inpatient stay in a hospital or specific high-risk conditions identified during a visit to an emergency room may be acceptable. Applications should describe the method and criteria that will be used to identify the target population, and outline the rationale for the specific practice-based model that is proposed.
- Q. In the practice-based model, would control groups be made up of patients with no current relationship to the provider organization? (12/1/04)
 - A. Yes. One of the fundamental assumptions in the practice-based model is that providers cannot apply different standards of treatment or treatment protocols to otherwise similar patients. The matched control group would, therefore, have to be drawn from a population of patients that does not have an established relationship with the providers participating in the intervention.
- Q. May provider-based applicants propose a longer enrollment period than the six months described in the solicitation? (12/1/04)
 - A. CMS will consider options that allow for a longer enrollment, or a "rolling" period of time. The specifics must be addressed in the application. CMS would require enrollment to cease with sufficient time to allow for stabilization of the intervention group, as well as analysis of claims and clinical benefits of the project. CMS anticipates the need for at least one year of a stable population and claims data, but the actual time frame will depend on the proposed project. A related FAQ addresses the issue of replacing beneficiaries who die.

Q. What should provider-based applicants include in a recruitment enrollment design? (12/1/04)

A. Applicants need to include not just the total number of beneficiaries expected to enroll, but details regarding expected population targets and dates when those targets will be achieved. Provider-based awardees with rolling enrollment, or recruitment programs, will need to guarantee enrollment milestones to assure CMS has sufficient sample size and claims data in both intervention and control groups each year and over the life of the project.

Q. Will CMS allow a two-pronged approach (a combined provider and population based) method to enroll beneficiaries? (12/15/04)

A. Yes, applicants may propose a method that would have two enrollment options. All proposals should include a detailed explanation of how beneficiaries will be assigned to control and intervention groups using claims-based criteria and without creating selection bias, regardless of the method proposed.

Q. Will CMS allow a provider-based intervention group with multiple sites, enrolling a smaller number of beneficiaries in each site and sufficient size overall? (12/15/04)

A. Yes, applicants may propose a project where provider offices, networks, hospitals and ambulatory care are not contiguous. All sites must apply the same criteria and intervention models. The applicant should provide population targets and dates for each site to assure there will be a sufficient number of beneficiaries. The evaluation analysis and financial shared savings formula will rely on the criteria and model being consistently applied to all sites.

Q. Will CMS allow a geographic overlap with the CMHCB Demonstration and other demonstrations (e.g., BIPA Disease Management) or the Chronic Care Improvement Program (CCIP)? (12/15/04)

A.CMS will allow applicants to propose intervention models in the same geographic area as other CMS demonstrations or programs, with some limitations.

For example, a number of states, cities and counties have demonstration projects and programs targeting Congestive Heart Failure and Coronary Artery Disease. In areas where established demonstrations or program agreements exist, CMS will allow CMHCB applicants to propose an intervention method using criteria targeting beneficiaries with other diagnoses.

NOTE: Applicants should be sensitive to the fact that beneficiaries living in the same geographic region may have declined to participate in other demonstrations, and may or may not be interested in the high cost demonstration.

The success of care management programs is dependent on the ability of organizations to work collaboratively with their enrollees' physicians. Applicants should be aware that physicians who have patients participating in existing demonstrations or CCIP may resist working with multiple organizations for different groups of their patients based on diagnosis.

As geographic areas for some current and upcoming demonstrations are carved out by county and diagnoses, it is not possible to post a complete list at this time. Applicants may email (cmhcbdemo@cms.hhs.gov) with specific geographic questions or call Randy Thomas at 410 – 786 – 6578.

Q. Will CMS allow applicants to select all beneficiaries without targeting select diagnoses? (12/15/04)

A. Applicants proposing a population-based model may select beneficiaries based solely on the high-cost criteria. In a provider-based model all patients who are Medicare fee-for-service beneficiaries meeting the selection criteria (claims-based data elements) may be included in the intervention group. However, proposals may not include diagnoses associated with CCIP or existing demonstrations where an overlap in geographic areas occurs.

Q. Will CMS consider awarding a physician-driven project in multiple high inpatient cost cities? (12/15/04)

A. CMS will consider awarding applications with an intervention method focusing on targeting high-cost inpatient beneficiaries, either in one locale or across geographic areas. We believe there are positive outcomes yet to be realized for clinical intervention and cost savings in an integrated health care delivery system or consortium of inpatient and ambulatory care providers.

Q. Will CMHCB Demonstration awardees be able to start enrolling beneficiaries by March 1, 2005? (12/15/04)

A. Actual implementation dates will vary by site and model selected, as well as the successful awardee's proposed timeline. The actual award date will depend upon the time required to conduct the contractual due diligence process, which is necessary to ensure potential awardees are fiscally sound and organizationally able to implement their proposal.

Q. Will CMS consider continuous enrollment (replacement) of beneficiaries? (12/15/04)

A. CMS agrees replacing beneficiaries may be an issue for certain projects and applicants should address this issue in their proposals. CMS understands that a certain percent of the beneficiaries enrolled in the CMHCB demonstration may die or otherwise become ineligible. The reduction in the number of active participants in the intervention group has implications for the evaluation of the intervention group and business aspect for the awardees. The extent, and methods, to which the beneficiaries enrolled in the demonstration may be replaced, or continuously enrolled, will be negotiated between CMS and the awardees.

Benefits, Services and Provider Contracts

Q. Will CMS allow awardees to waive the beneficiary co-payments for covered services? (11/10/04)

A. The enrollees in the CMHCB demonstration will continue to have the same benefits provided under the traditional Medicare FFS program, including cost-sharing rules for coinsurance, co-payments, and deductibles. The CMHCB demonstration will not waive program policies that would affect the processing of claims by intermediaries and carriers. An awardee may waive cost sharing amounts to the extent permitted under current Medicare policy.

Q. Will CMS allow the awardee to provide coverage of prescription drugs prior to the implementation of Medicare Part D in 2006? (11/10/04)

A. CMHBC applicants may provide a prescription drug benefit, but must include detailed information on how they would offer and pay for pharmacy coverage in their application. The cost of these benefits must be paid for by the CMHBC awardee out of any monthly fee that it receives from CMS. It would, therefore, be included in the awardee's costs when determining whether the savings targets are achieved. Depending on the specific provisions of a proposal, acceptance of a proposal may be contingent upon acceptance of additional financial requirements (e.g., reinsurance, reserve, or withhold requirements).

Q. Will CMS allow awardees to provide covered and/or non-covered services (e.g., transportation, personal assistance) to CMHCB beneficiaries? (11/10/04)

A. CMS expects that all covered benefits will be paid by CMS if the provider is a fee-for-service contracted entity. Non-covered benefits or services may be provided by the awardee, but will need to be fully described in the application. Any non-covered benefits and services provided by the awardee will be included in the awardee's costs when determining whether the savings targets are achieved. Depending on the specific

provisions of a proposal, acceptance of a proposal may be contingent upon acceptance of additional financial requirements (e.g., reinsurance, reserve, or withhold requirements).

- Q. Will CMS allow awardees to waive the requirement for a three-day inpatient hospitalization prior to admission to a skilled nursing facility or other exclusions and conditions of coverage under the FFS program? (11/10/04)
 - A. No. As indicated in the answer to an earlier question, the CMHCB demonstration will not waive program policies that would affect the processing of claims by intermediaries and carriers.
- Q. Would CMS allow awardees to provide primary care physicians an incentive for comanagement of their patients who are in the intervention group? (11/10/04)
 - A. Solely providing a financial incentive would not be permitted. An applicant may propose to provide a care management fee to participating physicians. The proposal should clearly identify such fees and describe the care management services to be provided by the beneficiary's primary care physician in return for the fee. Whatever arrangement is proposed must be permitted under current Medicare fraud and abuse regulations. Any care management fees paid to providers would be come out of the monthly fee paid to the CMHCB awardee and would be subject to the guaranteed savings.
- Q. Are applicants required to have all provider contracts signed and in place prior to the application due date? (12/1/04)
 - A. Applicants must show evidence of a provider network or supporting documentation indicating a viable plan to develop the necessary provider network. Contracts may be finalized after the award date, but no later than an agreed upon date (prior to implementation of the project) that is satisfactory to CMS and the awardee

Management and Contractual Issues

- Q. Will awardees be allowed to create the letters sent to potential demonstration beneficiaries? (11/10/04)
 - A. CMS will consult with the awardees to draft the initial beneficiary solicitation letter inviting beneficiaries to participate in the demonstration. CMS will determine the final content of that solicitation. The CMS project officer must review additional correspondence from the awardee to the beneficiary.

Q. Will awardees be allowed to contact primary care physicians regarding patients identified in the intervention group? (11/10/04)

A. Yes. However, the decision to participate in the CMHCB demonstration is the beneficiary's to make. If the beneficiary chooses not to participate in the demonstration, the awardee may not provide services on the beneficiary's behalf.

Q. Please describe the two methods that applicants may propose for forming intervention and control groups. (11/10/04)

A. The CMHCB demonstration will use two different methods of forming intervention and control groups. A proposal must indicate which approach will be used.

Under the first or population-based method, the applicant must specify the criteria that will be used to identify beneficiaries eligible to participate in the demonstration. CMS will identify beneficiaries meeting these criteria and randomly assign them to intervention and control groups. Beneficiaries assigned to the intervention group will be contacted by CMS and given an opportunity to opt out of the demonstration. A list of those beneficiaries who do not explicitly opt out of the demonstration will be forwarded to the awardee for follow-up and outreach. Outreach may be conducted in writing, by telephone, or face-to-face. The awardee will thus be able to contact beneficiaries who did not respond to the initial solicitation sent by CMS as well as those who responded affirmatively. The awardee will not be permitted to contact those beneficiaries who explicitly opted out of participation in the demonstration. CMS will provide an opportunity for the awardee to advise on the description of its program and other information that should be included in the initial CMS communication. Beneficiaries contacted for follow-up by the awardee who indicate that they are not interested in participating are not to be contacted again, but they will continue to be included in the intervention group even though they are not receiving any services from the awardee.

The second or practice-based method will allow a provider organization, or consortium, to enroll its own patients. Applicants must specify the criteria they will use to identify their patients so a matched control group of patients using other providers can be identified and used to measure the effectiveness of the awardee's intervention. The applicant's selection criteria must be clearly described with details regarding clinical, demographic and the potential number of beneficiaries to be included in the intervention group.

- Q. If a primary care physician wants to refer a patient qualifying for the demonstration but who was not listed in the original data set, would CMS allow the awardee to accept this patient with CMS then identifying a matched control? (11/10/04)
 - A. CMS will accept one of two approaches for the CMHCB demonstration (see question above). The formation of intervention and control groups must be done at the outset of the demonstration. Enrollment of additional beneficiaries will be conducted only in

accordance with procedures that are established for the replacement of enrollees who are lost to the demonstration because they die or otherwise stop meeting the eligibility criteria. These procedures must be described in the application and will be subject to further negotiation when negotiating the demonstration terms and conditions.

Evaluation

Q. Is the evaluation of the demonstration tied to the financial shared savings? (12/1/04)

A. The structure of the financial incentives and payment methodology are independent of the formal evaluation process. The financial shared savings and payment methodology are described in more detail in other FAQ and answers in this document.

The evaluation will measure quality, clinical management, beneficiary and provider satisfaction, as well as the ability to demonstrate ongoing savings. The evaluation will play a significant role in determining how or if the demonstration project will continue from one year to the next. CMS must assure the ongoing viability of the demonstration project by reviewing financial, quality and satisfaction parameters. Significant problems with an awardee being able to meet its targets will cause CMS to carefully review if the awardee can continue or if modifications may need to be implemented for ongoing management.

Q. What is the purpose of Evaluation? (12/1/04)

A. The formal evaluation has two purposes. One, to specifically test whether each program was able to achieve the demonstration objectives of improving quality of care and realizing financial stability. And secondly, the evaluation has a broader research objective for CMS to learn whatever it can about what makes these programs successful. The evaluation also includes an analysis of the program features which work best or which types of Medicare beneficiaries (subpopulations) are best served by the program.

Q. Will the programs be evaluated compared to each other? (12/1/04)

A. The primary comparisons for the evaluation will be within an individual site, rather than measuring one program against another. The intervention group for a particular site will be compared to a control population for that site. How the control group gets selected will depend on the model design. For example, it may be based on a geographic population of beneficiaries which gets randomized into an intervention and control group, or may be from a sample of beneficiaries who get matched to the patients in a practice-based intervention group.

Q. What will be included in the evaluation, and will CMS conduct it? (12/1/04)

- A. CMS will contract with an outside firm to conduct the evaluation, but retain the responsibility to oversee the project. Exact details about the evaluation will depend, in part, on the specifics of each awarded program design. Evaluation factors will include the following:
 - Clinical quality improvement
 - Beneficiary and provider satisfaction
 - Health outcomes
 - Financial savings to the Medicare program

Q. What data will be used to evaluate the program, and can applicants suggest criteria for control groups and satisfaction surveys? (12/1/04)

- A. We anticipate using a variety of data sources which may include, but not limited to, the following:
 - Site visits and interviews
 - Surveys of beneficiaries and providers
 - Clinical and case management data provided by the awardee
 - Data collected by the demonstration sites during operations
 - Medicare claims data for utilization and expenditures

Applicants are welcome to submit suggestions that apply to their targeted population. CMS, through its contractors, intends to use customized provider and beneficiary satisfaction survey tools and data sources. Criteria for the applicant's intervention group must be clearly stated, and similar data elements will be used for the control groups.

Q. Will the evaluations be conducted each year, or only at the end of the demonstration? (12/1/04)

A. We expect to conduct interim analyses as the projects unfold and are implemented, but the final evaluation will be based on the three-year experience of each site, allowing for sufficient time for claims to be processed and analyzed.